Remarks

I. Support for Amendments

Of the 9 original claims, non-elected claims 2-9 have been canceled without disclaimer of or prejudice to the underlying subject matter, and claim 1 has been amended. Claims 10-15 have been added. Support for the foregoing claim amendments may be found throughout the specification and in the original claims, for example at page 9, line 19 through page 10, line 4 and at page 19, lines 3-21. Upon entry of the foregoing amendments, claims 1 and 10-15 are pending in the application. No new matter enters by these amendments.

II. Restriction Requirement

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants also acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants respectfully disagree that the polynucleotide sequences of the instant application would be considered of the complexity that merits restriction to a single sequence in contradiction to the expressed USPTO policy of examining ten sequences, as set forth in the Manual of Patent Examining Procedure. (*See* MPEP, 8th ed., August 2001, Section 803.04, page 800-10). However, in order to facilitate prosecution, Applicants have removed non-elected sequences from the claims.

III. Sequence Listing

Applicants note and thank the Office for the acknowledgement that the computer-readable sequence listing was approved by STIC for matters of form. Office Action at page 3

IV. Objection to the Specification

The Examiner objected to Applicants' disclosure because it allegedly "contains an embedded hyperlink and or other form of browser-executable code." Office Action at page 3. Applicants have amended the specification to remove the alleged embedded hyperlinks and/or other forms of browser-executable code. No new matter enters by these amendments. The URL addresses themselves contained throughout the specification do not constitute browser-executable code in the absence of embedded hyperlinks and/or other forms of browser-executable code. The specification as amended does not contravene stated PTO policy of prohibiting live web links to other web pages, which might be commercial. (MPEP § 608.01 (d).)

V. Rejection under 35 U.S.C. § 101

Claim 1 was rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either specific and/or substantial utility or a well-established utility. Office Action at page 4. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "acquiring genes, identifying polymorphisms, determining plant traits, and DNA mapping." Office Action at pages 4-5. However, despite this admission and numerous uses cited throughout the specification, the examiner contends that none of these utilities constitutes a "substantial" or "specific" utility as defined in the Interim Guidelines. Applicants respectfully disagree. The application of the Interim Guidelines ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by

to obtain nucleic acid homologues, *etc.* (*see e.g.*, Specification, beginning at page 32, under heading "Uses of the Agents of the Invention").

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecule may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by stating that they are "generic in nature and applicable to a myriad of such compounds." Office Action at page 5. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 5. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107.01 ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is [illegible]

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. An invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. §101, and have done so in the present case, the rejection under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

VI. Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

Claim 1 was rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, an invention with no utility cannot be enabled). Office Action at page 6. Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

VII. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claim 1 was also rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Office Action at page 7. Applicants respectfully traverse this rejection.

The Examiner does not contest that Applicants have disclosed SEQ ID NO: 1 and, as such, have *per se* met the written description provision of 35 U.S.C. § 112, first paragraph with respect to this sequence. However, the Examiner contends that the specification "fails to describe any open reading frame, start stop codons, or encoded proteins for any SEQ ID NO, SEQ ID No: 1 in particular." Office Action at page 7. According to the Examiner, claim 1 lacks sufficient written description because "one can only envision the particular sequence disclosed and cannot envision any encoded protein

page 7. The Examiner appears to argue that Applicants have not adequately described the genus encompassed by the claims. However, such an assertion is unfounded.

As the Examiner notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989).

A related, and equally well-established principle of patent law is that claims "may be broader that the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe the molecules encompassed by the claims, it is not required that each and every aspect of those nucleic acid molecules (*e.g.*, an open reading frame) be disclosed. *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996) (Adequate written description is provided if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

Furthermore, an adequate written description of a genus of nucleic acid molecules, such as recited in claim 1, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to

genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The Office contends that "[t]he specification describes only the particular SEQ ID NO: 1 and not other sequences containing said sequence." Office Action at page 7. According to the Office's argument, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. Applicants respectfully disagree. The present claims define, with a high degree of specificity, chemical properties commonly possessed by members of the genus that distinguishes them from others. In particular, Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 1. Moreover, nucleic acid molecules falling within the scope of the present claims are readily identifiable – they comprise a nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the present specification. Accordingly, there is no deficiency in the written description support for claim 1.

On the basis of the foregoing, it is clear that claims 1 satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

VIII. Rejection of Claim 1 Under 35 U.S.C. § 102

Claim 1 has been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by the sequence of Database EST, accession number AI726728. Applicants respectfully traverse this rejection.

This reference does not anticipate claim 1. "It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech*

be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). AI726728 does not teach every element of the claimed invention.

In the present application, the presently amended claim 1 is directed to a substantially purified nucleic acid molecule that encodes a cotton protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1. The Examiner admits that AI726728 does not disclose the nucleic acid sequence of SEQ ID NO: 1. Rather, the Examiner alleges that "[t]he referenced sequence comprises multiple fragments of instantly claimed SEQ ID No: 1." Office Action at page 8.

The Examiner has applied an untenable interpretation of claim 1 to cover fragments of the specifically claimed nucleic acid molecule, and thus concludes that the claim is anticipated by the cited reference. A grammatically consistent interpretation of the claim at issue would relate the phrase "or fragment thereof" in the preamble back to the phrase "cotton protein" directly preceding it. Further, because the phrase "or fragment thereof" appears before the transition phrase "comprising", it is clear that it does not refer to a fragment of SEQ ID NO: 1. As such, claim 1 is directed to a nucleic acid molecule which encodes a cotton protein or fragment thereof, *i.e.*, a fragment of a cotton protein, comprising the nucleic acid sequence of SEQ ID NO: 1. Whatever else the reference cited by the Examiner teaches, it does not disclose SEQ ID NO: 1. Absent a teaching of each and every element of the claim, the reference cited by the Examiner does not anticipate pending claim 1.

Moreover, a rejection under 35 U.S.C. § 102 (a) is only proper if, *inter alia*, an anticipatory reference is available publicly. The Examiner has submitted no evidence that AI726728 was available to the public prior to Applicants' priority date. The Examiner apparently relies on the date the nucleotide sequence was submitted to the GenBank database to establish the reference date under § 102(a). However, there is no evidence that AI726728 was actually published or otherwise made available to the public

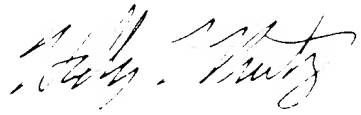
As such, claim 1 is not anticipated by the reference cited by the Examiner. Accordingly, for at least the foregoing reasons, the rejection of claim 1 under 35 U.S.C. § 102(a) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5000 with respect to any unresolved issues remaining in this application.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe that any fees are due at this time. However, if any fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, then the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2387, referencing docket number 16517.247.

Respectfully submitted,



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